

Medicine Quality Alert: Class II Medicine Recall of Dawaflox Powder for Oral Solution (Flucloxacillin 125mg/5ml) Batch No. 2301119 and 2401188

Dawa Ltd has initiated a voluntary recall of Dawaflox DPS (Flucloxacillin 125mg/5ml) 100ml Batch Nos 2301119 and 2401188

From: Pharmacy and Poisons Board

Date initiated: 3rd April 2025

Recall Reference Number: REC/2025/013

Recall Classification: Class II

Recall Level: Retail/Facility level

Manufacturer: Dawa Ltd Ltd, Kenya

Product name: Dawaflox Powder for Oral Solution

Active Pharmaceutical Ingredient: Flucloxacillin 125mg

Affected counties: All

Affected Batch

| Batch Number | Date of Manufacture | Date of expiry | Pack Size |
|---------------------|----------------------------|-----------------------|------------------|
| 2301119 | 01/2023 | 12/2025 | 100ml |
| 2401188 | 01/2024 | 12/2026 | 100ml |

Brief description of the problem

The product is being recalled due to failure to comply with the assay test observed during long-term stability studies. This was identified during GMP inspection.

Action for healthcare professionals

Quarantine all remaining stock and stop further distribution, sale, issuing or use of the above batches immediately. Await contact from Dawa Ltd to arrange the return.

Action for patients and caregivers

No further action is required by patients as this is a Retail/hospital Pharmacy and Wholesaler/Distributor level recall. You are advised to talk to your healthcare professional if you have the above batches of Dawaflox Powder for oral solution.

Further Information

For inquiries about consignments of the impacted batch, please contact Dawa Limited by email at: info@dawalifesciences.com or bhavisha.vora@dawalifesciences.com and by Telephone at: +254 713 275 777 or +254 733 764 747

You are advised to promptly report any case(s) of adverse events and suspected substandard and falsified products to the nearest healthcare facility or through the following channels:

- <https://pv.pharmacyboardkenya.org/users/mpublic>
- USSD code at *271#
- Email pv@ppb.go.ke or pms@ppb.go.ke
- Telephone No. 0795743049
- Mobile application: mPvERS both Android and iOS

For any further enquiries and feedback on the product recall, contact the post-marketing surveillance unit at the Pharmacy and Poisons Board via email at pms@ppb.go.ke

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